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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,211

10/30/2006

Bakulesh Mafatlal Khamar

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,211	<b>Applicant(s)</b> KHAMAR, BAKULESH MAFATLAL	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 7 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22-29, 32, 34, 36-43 and 45-54 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48-54 is/are allowed.
- 6) ☐ Claim(s) 22-29, 32, 34, 36-43 and 45-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1645

### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 7 January 2010, is acknowledged.

Claims 23, 45, 46 and 47 have been amended. New claims 48-54 have been added.

2. Claims 22-29, 32, 34, 36-43 and 45-54 are pending and under consideration.

### **Rejections Withdrawn**

3. The rejection of claims 45, 46 and 47 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the amendment of the claims.

### **Rejections Maintained**

4. The rejection of claims 22-27, 32, 34 and 36-43 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained.

Applicant argues that one of ordinary skill in the art could prepare solvent extracts of *M. w* with any of the listed solvents without undue experimentation.

The examiner has considered applicant's argument, but does not find it persuasive. The lack of enablement is not for simply preparing extracts, but utilizing said extracts in a method of treating, managing or preventing disease of the lungs. As put forth in the original rejection explanation, the only extracts which indicate such treatment are extracts produced utilizing the solvents chloroform, ethanol, methanol and acetone or utilizing the enzyme liticase. These limited examples do not provide sufficient support that all solvents listed or all enzymes listed result in extracts that fulfill the required methods of treatment, management or prevention.

5. The rejection of claims 28 and 29 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from rejected claims, is maintained for reasons of record.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1645

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Newly amended claims 45-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods utilizing extracts produced utilizing the solvents chloroform, ethanol, methanol and acetone or utilizing the enzyme liticase, does not reasonably provide enablement for methods utilizing extracts utilizing other solvents or enzymes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – as newly amended, the claims are drawn to a method of treating, managing or preventing obstructive lung disease comprising administering to a patient a pharmaceutical composition comprising an effective amount of: (a) heat killed whole cell *Mycobacterium w*, (b) sonicated *Mycobacterium w*, (c ) a solvent extract of *Mycobacterium w*, wherein the solvent is selected from chloroform, ethanol, methanol, acetone, phenol, isopropyl alcohol, acetic acid, urea, and hexane, or, (d) an enzymatic extraction of *Mycobacterium w*, wherein the enzyme is selected from liticase and pronase.

Art Unit: 1645

The state of the prior art as evidence by applicant's specification indicates that *Mycobacterium w*, while being utilized in treatment of leprosy, has not been utilized for other treatments. Thus, there is a lack of predictability in the art that any preparation of *Mycobacterium w* is effective for the treatment, management or prevention of lung disease.

The amount of direction/guidance/working examples in the specification is insufficient support for the scope of the instant claims. The only examples utilize extracts produced utilizing the solvents chloroform, ethanol, methanol and acetone or utilizing the enzyme liticase. The specification has not provided sufficient evidence that these few species of solvents or enzyme are reflective of any other type of solvent or enzyme extract which would result in the fulfillment of the requirements of the instant methods.

Thus, the quantity of experimentation necessary to determine which, if any, other solvents or enzymes would result in extracts which would be successful in the claimed methods, constitute merely an invitation to experiment without a reasonable expectation of success.

### Conclusion

7. Claims 22-29, 32, 34, 36-43 and 45-47 are rejected.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a)

Art Unit: 1645

will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

March 31, 2010